IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI CENTRAL DIVISION

ASTRAZENCA PHARMACEUTICALS LP,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**Case No. 2:24-cv-04143-MDH**
	)	
ANDREW BAILEY, in his official capacity as ATTORNEY GENERAL OF THE STATE OF MISSOURI; JAMES L. GRAY, in his official capacity as President of the Missouri Board of Pharmacy; CHRISTAN S. TADRUS, in his official capacity as Vice-President of the Missouri Board of Pharmacy; and DOUGLAS R. LANG, ANITA K. PARRAN, COLBY GROVE, TAMMY THOMPSON, and DARREN HARRIS, in their official capacities as members of the Missouri Board of Pharmacy,	)	
	)	
Defendants.	)	
	)	
v.	)	
	)	
MISSOURI HOSPTIAL ASSOCIATION, And MISSOURI PRIMARY CARE ASSOCIATION,	)	
	)	
Intervenors	)	

ORDER

Before the Court are State Defendant's Motion to Dismiss for Failure to State a Claim (Doc. 30) and Intervenor's Motion to Dismiss for Failure to State a Claim. (Doc. 68). Plaintiff has filed its suggestions in opposition. (Docs. 50 and 74). Both State Defendants and Intervenor Defendants (collectively "Defendants") have filed their replies. (Docs. 58 and 76). The matter is now ripe for adjudication. For reasons herein, Defendants' Motions are **GRANTED IN PART** and **DENIED IN PART**.

BACKGROUND

This case arises out of Senate Bill ("S.B.") 751 which created protections to the delivery of 340B drugs to contract pharmacies on behalf of "covered entities". Section 340B incentivizes pharmaceutical manufactures to provide qualified health care providers, referred to as "covered entities," with pricing discounts on certain drugs prescribed to individuals and families whose income falls below the federal poverty level. Covered entities have contracted with outside pharmacies or "contract pharmacies," for the distribution and dispensation of 340B drugs. S.B. 751 protects hospitals, federal qualified health centers ("FQHC"), and their patients from drug manufacturers' restrictions on the number of contract pharmacies a hospital or FQHC can use and still receive discount pricing under 340B plan. Plaintiff is a limited partnership organized under the laws of Delaware with its principal place of business in Wilmington, Delaware. State Defendants are all residents of Missouri that are responsible for administering and enforcing the provisions of S.B. 751. Intervenors Missouri Hospital Association and Missouri Primary Care Association are Missouri, not-for-profit member organizations.

Plaintiff alleges three Counts seeking declaratory relief that S.B. 751 is unconstitutional and injunctive relief barring enforcement of S.B. 751. Count I alleges S.B. 751 is preempted by federal patent laws under the Supremacy Clause. Count II alleges S.B. 751 violates the Contracts Clause of the U.S. Constitution and Count III alleges S.B. 751 violates the Takings Clause of the U.S. Constitution. Defendants argue S.B. 751 is not preempted by federal patent laws because S.B. 751 does not adjust 340B drug prices nor does it fit the requirements for conflict preemption. Defendants next argue Plaintiff has not pleaded facts that would give rise to relief of a violation of the Contracts Clause. Finally, Defendants assert that S.B. 751 neither forcibly takes property from Plaintiff nor is a regulatory taking.

STANDARD OF REVIEW

A complaint must contain factual allegations that, when accepted as true, are sufficient to state a claim of relief that is plausible on its face. *Zutz v. Nelson*, 601 F.3d 842, 848 (8th Cir. 2010) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). The Court "must accept the allegations contained in the complaint as true and draw all reasonable inferences in favor of the nonmoving party." *Coons v. Mineta*, 410 F.3d 1036, 1039 (8th Cir. 2005) (internal citations omitted). The complaint's factual allegations must be sufficient to "raise a right to relief above the speculative level," and the motion to dismiss must be granted if the complaint does not contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp v. Twombly*, 550 U.S. 544, 545 (2007). Further, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice. *Ashcroft*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555).

ANALYSIS

I. Count I – Preemption by Federal Patent Laws

Count I seeks declaratory and injunctive relief claiming S.B. 751 is preempted by federal patent laws under the Supremacy Clause of the United States Constitution. Specifically, federal patent laws conflict preempt S.B. 751. Defendants argue that Count I should be dismissed because S.B. 751 does not cap or fix drug prices, only the federal 340B program does. Additionally, Defendants argue that S.B. 751 does not otherwise fit the requirements for conflict preemption.

"Article VI of the Constitution provides that the laws of the United States 'shall be the supreme Law of the Land; … any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.'" U.S. Const. art. VI, cl. 2. State laws that conflict with federal law are "without

effect." *Cipollone v. Liggett grp., Inc.*, 505 U.S. 504, 516, 112 S.Ct. 2608, L.Ed.2d 407 (1992). Congress may preempt a state law through federal legislation, but where a federal statute does not refer expressly to preemption, Congress may implicitly preempt a state law. *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 376, 135 S.Ct. 1591, 191 L.Ed.2d 511 (2015). Congress may impliedly pre-empt state law "either through 'field' preemption or "conflict' preemption." *Id*. Conflict pre-emption exists where 'compliance with both state and federal law is impossible,' or where 'the state law stands as an obstacle to the accomplishment and execution of the full purposes and objections of Congress.'" *Id*. (quoting *California v. ARC Am. Corp.*, 490 U.S. 93, 100, 101, 109 S.Ct. 1661, 104 L.Ed.2d 86 (1989).

Plaintiff argues that S.B. 751 restricts the prices at which manufacturers can sell their patented drugs by requiring drug manufacturers to make 340B drugs available for unlimited contract pharmacy sales. (Complaint ¶ 64). Plaintiff asserts S.B. 751 functions as a price cap for an unlimited number of contract pharmacy sales that impermissibly constrains manufacturers' "opportunity" to take advantage of the benefit of exclusivity conferred by Congress "during the patent's term." *Id*. (quoting *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007).

The Eighth Circuit in *Pharm. Rsch. & Manufacturers of Am. v. McClain* reviewed a similar Arkansas statute where the plaintiff in that case argued an analogues Arkansas law set a price cap and thus was conflict preempted by a different federal law. The Eighth Circuit ruled the Arkansas law did not require manufactures to provide 340B pricing discounts to contract pharmacies nor does the state statute set or enforce discount pricing. *Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F. 4th 1136, 1145 (8th Cir. 2024), *cert. denied*, No. 24-118, 2024 WL 5011712 (U.S. Dec. 9, 2024). S.B. 751 likewise does the same thing as the Arkansas statute and does not require

manufacturers to extend the federal 340B discount to contract pharmacies. S.B. 751 which revised Mo. Rev. Stat. § 376.414 states:

> A pharmaceutical manufacturer, third-party logistics provider, or an agent or affiliate of such pharmaceutical manufacturer or third-party logistics provider, *shall not deny, restrict, or prohibit, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with, or otherwise authorized by, a covered entity to receive 340B drugs on behalf of the covered entity* unless such receipt is prohibited by the United States Department of Health and Human Services. A wholesale drug distributer, as defined in section 338.330, shall not be considered an agent or affiliate for purposes of this subsection.

Mo. Rev. Stat. § 376.414.2. (emphasis added). The statute by its plain terms only places restrictions on what pharmaceutical manufacturers or third-party logistic providers can restrict or prohibit regarding the acquisition or delivery of 340B drug to a contract pharmacy on a covered entity's behalf. The statute does not make any mention of exclusivity periods, patent terms, or even pricing discounts.

The 340B Program has specific enforcement measures that safeguards the prices at which manufacturers can sell their patented drug while also complying with the provisions of the 340B program. The discounted price or "ceiling price" a drug manufacturer may change in the 340B program is determined by statutory formula. 42 U.S.C. §§ 256b(a)(2), 1396r-8(c). Covered entities may only prescribe 340B discounted drugs to patients who qualify and may not request or receive duplicative 340B discounts and Medicaid rebates for the same drug. *Id*. § 256b(a)(5)(A)-(B). Additionally, covered entities may not engage in diversion of covered outpatient drugs through "resell[ing] or otherwise transfer[ring] the drug to a person who is not a patient of the [covered] entity." *Id*. § 256b(a)(5)(b).

Taking Plaintiff's allegation as true for the purposes of a motion to dismiss it has failed to show a right to relief above a speculative level. Covered entities cannot prescribe discounted 340B

drugs except to those who qualify under the program. Both the plain language of the statute as well as precedent within the Eighth Circuit has established that statutes akin to S.B. 751 do not directly regulate the pricing of 340B drugs as regulation of pricing is determined by the federal 340B statute. Further, S.B. 751 does not require manufacturers to give the 340B discount to contract pharmacies. As such S.B. 751 does not conflict preempt federal patent laws under the Supremacy Clause. For the reasons stated, Defendant's Motion to Dismiss on Count I are **GRANTED**.

II. Count II – Violation of the Contracts Clause

Count II seeks declaratory and injunctive relief alleging S.B. 751 violates the Contracts Clause of the U.S. Constitution. Specifically, S.B. 751 substantially impairs the pharmaceutical pricing agreements ("PPA") entered to participate in the federal 340B program and that the State of Missouri has no legitimate justification for requiring unlimited contract pharmacy arrangements. Defendants argue that Plaintiff has not pleaded facts that would give rise to relief of a violation of the Contracts Clause.

The Contract Clause of the United States Constitution provides that no state shall "pass any law impairing the Obligation of Contracts." U.S. Const. art. I, § 10, cl. 1. A three-part test determines whether state action violates the Contract Clause. First the court asks whether "the state law has, in fact, operated as a substantial impairment on pre-existing contractual relationships." *Am. Fed'n of State, Cnty. & Mun. Emps. v. City of Benton, Arkansas*, 513 F.3d 874, 879 (8th Cir. 2008) (quoting *Equip. Mfrs. Inst. V. Janklow*, 300 F.3d 842, 850 (8th Cir. 2002). The first prong involves a three-part inquiry: "(1) whether there is a contractual relationship; (2) whether a change in law impairs that contractual relationship; and (3) whether the impairment is substantial." *Gen. Motors Corp v. Romein*, 503 U.S. 181, 186, 112 S.Ct. 1105, 117 L.Ed.2d 328 (1992). If substantial impairment existed, the court will determine whether the state has a "significant and legitimate

public purpose behind the regulation." *Educ. Employees Credit Union v. Mut. Guar. Corp.*, 50 F.3d 1432, 1438 (8th Cir. 1995). If there is no significant and legitimate public purpose, the state law is unconstitutional under the Contract Clause. *See Equip. Mfrs.*, 300 F.3d at 850. If, however the state identifies such a public purpose, the court will consider "whether the adjustment of the rights and responsibilities of contracting parties is based upon reasonable conditions and is of a character appropriate to the public purpose justifying the legislation's adoption." *Energy Reserves Group, Inc. v. Kan. Power & Light Co.*, 459 U.S. 400, 412, 103 S.Ct. 697, 74 L.Ed.2d 569 (1983).

Taking as true Plaintiff's allegations for the purpose of a motion to dismiss, it has raised its right to relief above a speculative level. Plaintiff alleges that it signed a PPA to participate in the federal 340B program. (Complaint ¶ 69). As part of the terms of the PPA is the requirement that manufacturers offer discounted drugs only to a specifically delineated set of covered entities. *Id*. Neither the 340B statute nor the PPA requires drug manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies. *Id*. Plaintiff claims that S.B. 751 expands its obligations under the PPA to unlimited contract pharmacies thus causing a substantial impairment of Plaintiff's expectation of the 340B program. (Complaint ¶ 70). Plaintiff further argues that the State of Missouri has no legitimate justification for requiring unlimited contract pharmacy arrangements. Plaintiff states its policy already ensures that every covered entity is offered those drugs at a discount and that its polices allow covered entities to designate a single contract pharmacy if it does not have an on-site pharmacy to dispense the 340B drugs. (Complaint ¶ 72). Additionally, Plaintiff argues that S.B. 751 will advance the economic interest of for-profit entities without a cost-reduction for patients. (Complaint ¶¶ 73 and 74).

Taking as true Plaintiff's allegations, it has raised a right to relief above a speculative level. Plaintiff has sufficiently alleged the existence of a contract, that would be substantially impaired

by S.B. 751. For the reasons stated, Defendants' Motion to Dismiss on Count II of Plaintiff's Complaint is **DENIED**.

III. Count III – Violation of the Takings Clause

Count III alleges that S.B. 751 violates the Takings Clause by a physical appropriation of manufactures prescription drugs by contract pharmacies and covered entities. Alternatively Count III alleges if not a physical appropriation, it would still constitute a regulatory taking. Defendants argue that S.B. 751 neither forcibly takes property from Plaintiff nor is a regulatory taking.

The Takings Clause of the Fifth Amendment to the Constitution, which is "applicable to the States through the Fourteenth Amendment," provides: "[N]or shall private property be taken for public use, without just compensation." U.S. Const. Amend. V. Takings claims are recognized as to both personal property, including goods, and real property. *Horne v. Dep't of Agriculture*, 576 U.S. 350, 358 (2015). A taking can be either per se or regulatory, both of which entitle the property owner to just compensation. *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 147-49, 141 S. Ct. 2063, 2071, 210 L. Ed. 2d 369 (2021). A per se taking occurs "[w]hen the government physically acquires private property for a public use," including "when the government physically takes possession of property without acquiring title to it." *Id*. at 147. A taking can also occur as a result of "the deprivation of the former owner rather than the accretion of a right or interest to the sovereign." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 968, 1005-06 (1984). The Supreme Court has held that a regulatory taking occurs when a regulation "goes too far" in limiting an owner's use of her property. *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 415, 43 S. Ct. 158, 67 L.Ed. 322 (1922).

a. Physical Appropriation

Defendants argue that S.B. 751 does not forcibly take any property from Plaintiff or compel a transfer of title to contract pharmacies and thus Plaintiff's argument for a physical appropriation of private property must fail. Further, Defendants argue that because Plaintiff has voluntarily participated in the federal 340B program it cannot give rise to an unconstitutional taking. Plaintiff argues that S.B. 751 takes the private property of drug manufacturers to transfer their prescription drugs to private entities, covered entities and the pharmacies with which they contract. (Complaint ¶ 78). Plaintiff asserts this forced transfer results in the physical appropriation of manufacturers' prescription drugs by contract pharmacies and covered entities, and it therefore constitutes a per se taking. (Complaint ¶ 80).

When an entity voluntarily participates in a federal program, it forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation. *Se. Arkansas Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016) (quoting *Minnesota Ass'n of Health Care Facilities, Inc.*, 742 F.2d at 446 (8th Cir. 1984)). As described above, Plaintiff has voluntarily agreed to be a part of the federal 340B program. Plaintiff signed a PPA to participate in the federal 340B program. (Complaint ¶ 69). As part of the terms of the PPA is the requirement that manufacturers offer discounted drugs only to a specifically delineated set of covered entities. Plaintiff voluntarily chose to participate in a federal program, and as Eighth Circuit precedent has noted, it forecloses the possibility that the federal 340B program, or S.B. 751, results in an imposed taking of private property which would give right to the constitutional right of just compensation. For the reasons stated Defendants' Motions to Dismiss Plaintiff's Physical Appropriation Claim is **GRANTED**.

b. Unconstitutional Regulatory Taking

Defendants argue that S.B. 751 is not an unconstitutional regulatory taking because Plaintiff has failed to allege facts showing it is a taking under the *Penn Central* test. Plaintiff argues that S.B. 751 has (1) a profound economic impact on the value of the property subject to the law; (2) significantly interferes with its investment-backed expectations; and (3) forces Plaintiff to transfer title to their property, depriving them of full use and enjoyment of said property.

The default test for determining whether a regulation constitutes a taking is known as the *Penn Central* Test. The *Penn Central* Court crafted a test that focuses largely "upon the particular circumstances [in each] case." *Becker v. City of Hillsboro, Missouri*, 125 F.4th 844, 852 (8th Cir. 2025) (quoting *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 130-31, 98 S.Ct. 2646, 2662, 57 L. Ed. 2d 631 (1978)).Under the *Penn Central* balancing test, courts consider: (1) "the economic impact of the regulation on the claimant," (2) "the extent to which the regulation has interfered with distinct investment-back expectations," and (3) "the character of the government action." *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 130-31, 98 S.Ct. 2646, 2662, 57 L. Ed. 2d 631 (1978).

While Plaintiff has not specified in its third count the specific facts to illustrate the elements of a *Penn Central* taking, the Complaint does allege facts that allows the Court to consider this claim at the motion to dismiss stage of the litigation. Plaintiff alleges that the economic impact of the regulation stems from the below market costs the 340B drugs costs Plaintiff by providing them to covered entities and contract pharmacies. (Complaint ¶¶ 95-96). Plaintiff argues that it joined the 340B program with the expectation and understanding that it would be required to provide discounted drugs only for a limited category of sales to covered entities and accepted that obligation when it joined the federal 340B program. (Complaint ¶ 70). Lastly, Plaintiff argues that Missouri has no legitimate justification for requiring unlimited contract arrangements, which will

advance the economic interest of for-profit entities at the expense of drug manufacturers. (Complaint ¶ 73).

Taking these allegations as true for the purpose of a motion to dismiss, Plaintiff has failed to raise a right to relief above a speculative level. A reasonable investment-backed expectation requires "more than a 'unilateral expectation or an abstract need.'" *Becker v. City of Hillsboro, Missouri*, 125 F. 4th 844, 858 (8th Cir. 2025) (quoting *Ruckelshaus v. Monsanto Co.*, 467 U.S. 968, 1005, 104 S.Ct. 2862, 81 L.Ed.2d 815 (1984)). The reasonableness of an expectation may be shaped by "the regulatory regime in place at the time the claimant acquires the property." *Id*. (quoting *Palazzolo v. Rhode Island*, 533 U.S. 606, 633, 121, S. Ct. 2448, 2465, 150 L. Ed. 2d 592 (2001)). The 340B program "is silent about delivery" and distribution of pharmaceuticals to patients. *Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F. 4th 1136, 1142 (8th Cir. 2024), cert. denied, No. 24-118, 2024 WL 5011712 (U.S. Dec. 9, 2024) (quoting Sanofi Aventis U.S. LLC v. *United States Dep't of Health & Hum. Servs.*, 58 F.4th 696, 702 (3d Cir. 2023), *judgment entered*, No. 21-3167, 2023 WL 1325507 (3d Cir. Jan. 30, 2023). Investment-backed expectations are often "informed by the law in force in the State in which the property is located." *Id*. (quoting *Ark. Game & Fish Comm'n v. United States*, 568, U.S. 23, 38, 133 S.Ct. 511, 184 L.Ed.2d 417 (2012)). The practice of pharmacy is an area traditionally left to state regulation. *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 972 (8th Cir. 2021).

Here, the regulatory regime in place when Plaintiff entered the 340B program was silent about delivery. States were free to change delivery and acquisition requirements regarding 340B drugs in their respective jurisdictions. This is consistent with the idea that the practice of pharmacy is an area traditionally left to state regulation. Plaintiff did not have a reasonable investment-backed expectation that states would not, at some point, deicide to change requirements of the

340B program that Congress had deliberately left silent in an area that is traditionally left to the states to regulate. As such, Plaintiff has not demonstrated a reasonable investment-backed expectation.

Further, Plaintiff has not shown the character of the government action is that of a regulatory taking. The inquiry into character of the government action focuses on "whether it amounts to a physical invasion or instead merely affects property interests through 'some public program adjusting the benefits and burdens of economic life to promote the common good.'" *Becker v. City of Hillsboro, Missouri*, 125 F. 4th 844, 859 (8th Cir. 2025) (quoting *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 539, 125 S. Ct. 2074, 2082, 161 L. Ed. 2d 876 (2005)). As discussed above regarding a physical appropriation, S.B. 751 does not create any new obligation outside of the federal 340B program except with regard to delivery and acquisition of 340B drugs to contract pharmacies. S.B. 751 was intended to ensure delivery of 340B drugs to covered entities and contract pharmacies to which help disseminating the drugs to those patients who are qualified through the federal 340B program. As such, the character of the government action does not suggest a physical taking but merely adjusting the benefits and burdens of economic life to promote the common good. For the reasons stated, Defendants' Motion to Dismiss Count III as a regulatory taking is **GRANTED**.

CONCLUSION

For reasons herein, Defendants' Motions to Dismiss are **GRANTED IN PART** and **DENIED IN PART**. Defendants' Motions to Dismiss Count I are **GRANTED**. Defendants' Motion to Dismiss Count II are **DENIED** and Defendants' Motion to Dismiss Count III are **GRANTED**.

IT IS SO ORDERED.

DATED: February 27, 2025

/s/ Douglas Harpool
DOUGLAS HARPOOL
UNITED STATES DISTRICT JUDGE